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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,218	01/04/2002	Tom Mc Hale	12013/58801	3450

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KENYON & KENYON
1500 K STREET NW
SUITE 700
WASHINGTON, DC 20005

EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,218

Applicant(s)

MCHALE ET AL.

Examiner

(Jackie) Tan-Uyen T. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-22 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 4/11/05 have been fully considered but they are not persuasive. Applicants argue that none of the cited references disclose or suggest "the number of folds being selected to reduce the deformation of coating of the medical implant caused by the expansion of the multi-wing balloon during expansion of the coated medical implant." The introductory statement of intended use and all other functional statements such as "the number of folds being selected to reduce the deformation of coating of the medical implant caused by the expansion of the multi-wing balloon during expansion of the coated medical implant" have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the device of Hossainy et al. in view of Fischell et al. which is capable of being used as claimed if one desires to do so. Apparatus claims must be structurally distinguishable from the prior art (See MPEP 2114).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 4, 5, 7, 12-15, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (6,153,252) in view of Fischell et al. (5,792,172).

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Hossainy et al. disclose a balloon-expandable stent including a plurality of cell (fig. 1-3), the stent being coated with a polymer layer containing therapeutic material (col. 3 to col. 6). Although, Hossainy et al. fails to disclose a balloon catheter having a multi-wing balloon for delivering the stent to a treated site, attention is directed to the Fischell et al. reference which teach a balloon with multifold for multi-wing for delivering a stent including a plurality of cells to a treated site, wherein the number of folds or wings of the balloon is the same as the number of the stent cells for improving the uniformity of stent cell expansion (col. 2, line 25 to col. 3, line 17). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a catheter balloon as disclosed by Fischell et al. for delivering the stent of Hossainy et al. in order to improve the uniformity of stent cell expansion. Doing so would meet all the limitation of the claims

In regarding to claim 5, the number of folds provided in the multi-wing balloon inherently affects the coating on the coated medical implant. The limitation "related to the coating" is considered as the effect of the multi-wing on the coating.

In regarding to claim 22, since the balloon as disclosed by Fischell et al. having smooth external surface. There is no structure different between the claimed polished external surface and the smooth external surface of Fischell's balloon. NOTE: The introductory statement of intended use and all other functional statements such as "polished" have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the device of Hossainy et al. in view of Fischell et al.

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4. Claims 3, 8, 9, 11 and 17-20, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. '252 in view of Fischell et al. (5,792,172) further in view of Hillstead (5,116,318). Although, the teaching of Hossainy et al. in view of Fischell et al. fails to disclose a removable elastic membrane encircling the multi-wing balloon before crimping a coated stent onto the multi-wing balloon, attention is directed to the Hillstead reference which teaches an removable elastic membrane encircling the multi-wing balloon before crimping a coated stent onto the multi-wing balloon in order to provide protection to the balloon and to eliminate a blade-like or wing-like shape in a deflated configuration of the balloon so that to eliminate the possibility of trauma to a blood vessel (col. 2, lines 25-49; col. 3, line 48 col. 5, line 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an elastic membrane as disclosed by Hillstead into the balloon catheter of Fischell et al. for delivering the stent of Hossainy et al.. in order to provide a better delivery system which eliminates the possibility of trauma to a blood vessel being treated and doing so would meet the method steps of claims 8, 11 and 18-20, as placing the elastic membrane disclosed by Hillstead on the multi-wing balloon of Fischell et al., the surface of the multi-wing balloon would be smooth or polished as the elastic membrane eliminate "blade-like" or "wing-like" and the adhesion between the balloon and the coating would be prevented (the coated stent would only contact the membrane).

5. Claims 8, 10, 18 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. '252 in view of Fischell et al. (5,792,172) further in

view of Euteneuer et al. (5,147,302). Although, the teaching of Hossainy et al. and Fischell et al. do not explicitly disclose the multi-wing balloon being pre-treated such as heating the multi-wing balloon to reduce the multi-wing balloon surface profile, attention is directed to the Euteneuer et al. reference which teaches before placing a tubular sleeve on to a multi-wing balloon, reducing the profile of the multi-wing balloon by partially folding multi-wings of balloon around a core and heating the partially folded balloon to cause the wings to fold or wrap further around a core so that the balloon is more tightly wrapped than it was prior to the heat treatment in order to install the sleeve over the balloon more easily (col. 3, lines 53-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to pre-treat the multi-wing balloon of Fischell et al. by heating the multi-wing balloon in order to reduce the profile of Fischell et al.'s balloon for facilitating ease of installation of Hossainy et al.'s stent. Doing so would reduce the adhesion between the balloon and the coated stent and the balloon with smaller profile would reduce the contact between the surface of the balloon and the inner surface of the stent as the stent installed over the balloon.

6. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. '252 in view of Fischell et al. (5,792,172) further in view of Hillstead '318 further in view of Trotta et al. (5,290,306) and Jung et al. (5,352,236). Although, the teaching of Hossainy et al. in view of Fischell et al. further in view of Hillstead fails to disclose an elastic membrane being pre-treated on outside and inside surfaces to reduce the adhesion between the coated stent and the membrane and between the

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membrane and the balloon, attention is directed the Trotta et al. and Jung et al. references which teach coating a lubricant on the inner or outer surface of an object in order to provide ease insertion. Jung et al. teach placing a lubricious material on an inner surface of a tubular sleeve in order to permits easy insertion of a wrapped balloon into the sleeve (col. 4, lines 36-44) and Trotta et al. teach placing a lubricant on the surface of a sleeve on a balloon in order to provide easy insertion of the balloon and the balloon may be carry an expandable stent (col. 2, lines 32-44 and col. 3, lines 6-13 and col. 4, lines 55-59). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a lubricious material on the inner and outer surface of the elastic membrane in order to provide easy insertion of the stent onto the sleeve or the balloon into the sleeve.

Allowable Subject Matter

7. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art fails to disclose or suggest the number of folds selected for the multi-wing balloon has an inverse relationship to the softness of the coating of the medical implant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731

June 21, 2005